REMARKS

Claims 17-23 and 25-37 are pending in the present application. Claim 29 has been amended. Support for the amendment to Claim 29 can be found throughout the specification as originally filed. Entry of the amendment and reconsideration is respectfully requested.

Rejection Under 35 U.S.C. §112

Claim 29

Claim 29 was rejected for allegedly being indefinite. Claim 29 has been amended to clarify that the microarray comprises a solid support. Applicants submit that this amendment makes the claim fully definite and request withdrawal of the rejection under 35 U.S.C. §112.

Rejections Under 35 U.S.C. §102(b)

Claims 17-23, 25-27 and 29-37

Claims 17-23, 25-27 and 29-37 were rejected under 35 U.S.C. §102(b) as allegedly being anticipated by Brennan (U.S. Patent No. 5,474,796). The Examiner states that Brennan teaches "an array representing every possible permutation of the 10-mer oligonucleotide." Office Action at p.3. Applicants respectfully disagree.

To be anticipatory under 35 U.S.C. § 102, a reference must teach each and every element of the claimed invention. *See Hybritech Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1379 (Fed. Cir. 1986). "Invalidity for anticipation requires that all of the elements and limitations of the claim are found within a single prior art reference. ...There must be no difference between the claimed invention and the reference disclosure, as viewed by a person of ordinary skill in the field of the invention." *See Scripps Clinic & Research Foundation v. Genentech, Inc.*, 927 F.2d 1565 (Fed. Cir. 1991).

In Example 4 of U.S. Patent No. 5,474,796, Brennan teaches "Use of Oligonucleotide Array Plates to Determine the Nucleotide Sequence of a Target Nucleic Acid." In this example, Brennan describes an array of 10-mer oligonucleotides synthesized "such that each oligonucleotide element, moving in a 5'-3' direction, is identical to the preceding element in nucleotide sequence, except that it deletes the 5'-most nucleotide, and adds a new 3'-most

nucleotide. In this way the total array represents every possible permutation of the 10-mer oligonucleotide." U.S. Patent No. 5,474,796, Example 4, column 9, lines 49-55.

However, Brennan does not teach "an array representing every possible permutation of the 10-mer oligonucleotide" in an unlimited context as suggested by the Examiner. Rather, Brennan teaches the construction of 10-mer oligonucleotides complementary to a known target nucleic acid. By "moving in a 5'-3' direction ... delet[ing] the 5'-most nucleotide, and add[ing] a new 3'-most nucleotide" along the sequence of a known target nucleic acid, Brennan teaches one of skill in the art to construct every possible permutation of a 10-mer oligonucleotide complementary to a known target nucleic acid. *Id.*, at column 9, lines 49-54. Brennan demonstrates this concept in Figure 1c by constructing every possible permutation of a 3-mer oligonucleotide complementary to the target nucleic acid ATTCTTGTTA. *Id.*, at Fig. 1c. Although Figure 1c only demonstrates the construction of 3-mer oligonucleotides complementary a known target nucleic acid, Example 4 extends this teaching to the construction of every possible permutation of a 10-mer oligonucleotide complementary a known target nucleic acid.

It would be illogical to teach such a method for "moving in a 5'-3' direction ... delet[ing] the 5'-most nucleotide, and add[ing] a new 3'-most nucleotide" (as in Figure 1c and Example 4) if one simply intended to make every possible permutation of a 10-mer oligonucleotide outside the context of a particular target nucleic acid—to do so, one of skill in the art would simply vary the nucleotides at each position of a 10-mer oligonucleotide (*e.g.*, using a simple algorithm) to generate all 1,048,576 possible 10-mer oligonucleotides in the human genome. *Id.*, at column 9, lines 49-54. For this reason, Brennan does not teach an array having oligonucleotides corresponding to the claimed CDH23, MYO7A, OTOF, SLC26A4 and USH2A genes either directly or inherently.

Further, Brennan does not teach the limitations of Claim 17 (or the claims dependent therefrom). For example, Brennan does not teach "a diagnostic microarray," does not teach "a set of hearing loss sequences," does not teach that the hearing loss sequences "are indicative of presence or absence of an allele associated with a risk for hearing loss," and does not teach that the set "consists essentially of genetic sequences found in CDH23, MYO7A, OTOF, SLC26A4 and USH2A genes" (emphasis added).

Because Brennan fails to disclose each and every limitation of Claim 17, these claims and the claims depending therefrom (*i.e.*, Claims 18-23, 25-37) are novel under 35 U.S.C. § 102(b). Applicants therefore respectfully request withdrawal of the rejection under 35 U.S.C. § 102(b) and allowance of the pending claims.

Rejections Under 35 U.S.C. §103(a)

Claims 17, 22-23, 25-27, 29-30 and 33

Claims 17, 22-23, 25-27, 29-30 and 33 were rejected under 35 U.S.C. §103(a) as being unpatentable over Morton *et al.* (*Human Molecular Genetics*, 2002, Vol. 11, p. 1229) in view of Choo *et al.* (*The Journal of Pediatrics*, February 2002, p. 148).

Independent Claim 17 and dependent claims therefrom (*i.e.*, Claims 18-23 and 25-37) are directed to diagnostic microarrays comprising nucleic acid sequences, where the sequences comprise a set of hearing loss sequences that "consists essentially of genetic sequences found in CDH23, MYO7A, OTOF, SLC26A4 and USH2A genes" (emphasis added).

The Examiner states that "[t]he language of 'comprising' and 'consist essentially' of is open claim language and as such the microarray can include any number of nucleic acid sequences along with the nucleic acid sequences found in CDH23, MYO7A, OTOF, SLC26A4 and USH2A." Office Action at p. 11 (emphasis added). The Examiner further states that because "[t]he combination of Morton and Choo does not require the prioritization of the hearing loss mutations in Morton et al. because the 35 USC 103(a) rejection presented above asserts that it would be prima facie obvious to one of ordinary skill in the art at the time of filing to place known nucleic acid sequences of mutations involved in hearing loss onto an [*sic*] microarray to determine the risk of hearing loss." *Id.*

However, as set forth in Section 2111.03 of the M.P.E.P., the transitional phrase "consisting essentially of" has a well-established meaning that occupies a middle ground between claims that recite the transitional phrase "consisting of," which exclude all materials other than those recited in the claim, and claims that recite the transitional phrase "comprising," which do not exclude additional, unrecited elements. *See Atlas Powder Co. v. E.I. DuPont de Nemours & Co.*, 750 F.2d 1569, 224 (Fed. Cir. 1998). The transitional phrase "consisting essentially of ... limits the scope of a claim to the specified materials or steps" by excluding additional materials or

steps that "materially affect the basic and novel characteristics of the invention." *In re Herz*, 537 F.2d 549, 551-52, 190 USPQ 461, 463 (CCPA 1976) (emphasis in original and added). *See*, M.P.E.P. § 2111.03.

As discussed in Applicants' response to the last Office Action, the basic and novel characteristic of the claimed microarrays is the selection of hearing loss sequences specifically found in CDH23, MYO7A, OTOF, SLC26A4 and USH2A genes. Morton *et al.* provide a generic list of 58 genes associated with hearing loss. The list provides numerous genes that Applicants' claims do not rely on. Because Morton *et al.* recite only an extensive list of genes, many of which are not specifically recited by Applicants' claims, one of ordinary skill in the art would *not* know to select the specific genetic sequences as recited in Claim 17 and dependent claims therefrom.

In view of the above, Applicants respectfully request that the Examiner reconsider and withdraw the rejection of Claims 17, 22-23, 25-27, 29-30 and 33 under 35 U.S.C. § 103(a) as being unpatentable over Morton *et al.* in view of Choo *et al.*.

Claims 18-21, 28, 31-32 and 34-37

Claims 18-21, 32 and 34-37 were rejected under 35 U.S.C. §103(a) as being unpatentable over Morton *et al.* in view of Choo *et al.* as applied to Claims 17, 22-23, 25-27, 29-30 and 33 in view of Weston *et al.* (*American Journal Human Genetics* 1996 Vol. 59, p. 1074). Claim 28 was also rejected under 35 U.S.C. §103(a) as being unpatentable over Morton *et al.* in view of Choo *et al.* as applied to Claims 17, 22-23, 25-27, 29-30 and 33 in further view of Hogan *et al.* (U.S. Patent No. 5,541,308). Finally, Claim 31 was rejected under 35 U.S.C. §103(a) as being unpatentable over Morton *et al.* in view of Choo *et al.* as applied to Claims 17, 22-23, 25-27, 29-30 and 33 in further view of Chee *et al.* (WO1995/011995).

As discussed above, one of ordinary skill in the art would *not* know to select the specific genetic sequences as recited in Claim 17 and dependent claims therefrom (*i.e.*, Claims 18-23 and 25-37) in view of Morton *et al.* (*Human Molecular Genetics*, 2002, Vol. 11, p. 1229) and Choo *et al.* (*The Journal of Pediatrics*, February 2002, p. 148). Applicants therefore respectfully request that the Examiner reconsider and withdraw the rejection of Claims 18-21, 28, 31-32 and

34-37 under 35 U.S.C. § 103(a) as being unpatentable over Morton *et al.* in view of Choo *et al.*, and in further view of Weston *et al.*, Hogan *et al.* and Chee *et al.*.

Conclusion

For the foregoing reasons, it is respectfully submitted that the rejections set forth in the outstanding Office Action have been addressed and that the application is in condition for allowance. Accordingly, Applicants request the expeditious allowance of the pending claims.

The undersigned has made a good faith effort to respond to all of the rejections in the case and to place the claims in condition for immediate allowance. Nevertheless, if any undeveloped issues remain or if any issues require clarification, the Examiner is invited to call the undersigned attorney to resolve such issues promptly.

Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

KNOBBE, MARTENS, OLSON & BEAR, LLP

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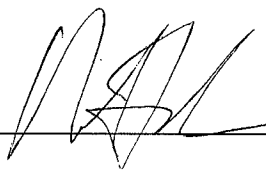
By: 

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